

**Remarks**

The Office Action mailed June 16, 2003 has been received and reviewed. Claims 1-4, 6, 9, 11, 12, 14-16, 18, and 22 having been amended, claims 25-47 and 49-99 canceled, and claims 100-108 having been added, the pending claims are claims 1-24, 48, 100-108.

Reconsideration and withdrawal of the rejections are respectfully requested.

The specification has been amended to clarify the results of an example. The claims have been amended to clarify the intended meaning of "metabolically active," and to clarify the meaning of the term integral with respect to the biological material. These amendments would be understood by anyone of skill in the art upon reading the specification.

**Information Disclosure Statement - PTO-1449 Forms**

Applicants request that a copy of the PTO-1449 forms submitted on May 17, 2001, marked as being considered by the Examiner, be returned with the next Official Communication. As a courtesy, a copy of the PTO-1449 forms submitted May 17, 2001 is enclosed (Exhibit A), along with a copy of the PTO date-stamped postcard (Exhibit B). Copies of the cited references are not included as they were provided to the Patent Office with the original PTO-1449 on May 17, 2001.

**The 35 U.S.C. §112, Second Paragraph, Rejection**

The Examiner rejected claims 9 and 15 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner stated that the phrase "fill in" is vague and indefinite because it is unclear how to optimize for this "purported purpose." This is respectfully traversed.

One of skill in the art would clearly understand that this is a property of the cell line (as opposed to a purpose), that of surviving desiccation or a drying process. One purpose of recombinant technology is to modify properties of biological material. Thus, a recombinant cell can be modified to be desiccation tolerant. The language of claim 9 has been clarified, however,

to remove the term "optimized" and to simply refer to the recombinant cell as being desiccation tolerant.

With respect to claim 15, the Examiner asserted that for a cell to be biologically active, the cells must be hydrated, and that claim 15 is vague and indefinite because of the language "wherein the biostructure is non-hydrated." This rejection is respectfully traversed.

It is submitted that cells can survive or be modified to survive a desiccation or drying process. Thus, the biostructure of the present invention can include cells that are or can become metabolically active even if the biostructure has been desiccated or dried and in a non-hydrated state. See, for example, page 8, line 32 through page 9, line 8. Thus, claim 1 has been clarified accordingly.

### **The 35 U.S.C. §102 Rejections**

The Examiner rejected claims 1, 6-8, and 10 under 35 U.S.C. §102(b) as being anticipated by Ishizaki (U.S. Patent No. 5,026,641). The Examiner rejected claims 1, 6-8, and 10 under 35 U.S.C. 102(a) as being known to the public in view of a condom. These rejections are rendered moot in view of the amendments to claim 1 and are respectfully traversed. The cited "devices" are not composite biological devices comprising a biostructure comprising at least one biological material as an integral imbedded component thereof. These terms must be read in light of the specification, which clearly exemplifies composite biological devices including a biostructure with imbedded biological material as an integral component thereof. The Ishizaki "device" is not a composite in the sense that the components are integral to each other (i.e., essential components) such that they are not readily separable, as in the composite device of the present invention. Also, in the condom test device, the "device" is not a composite device, nor is the biological material an integral imbedded component of the biostructure. Thus, withdrawal of these rejections is respectfully requested.

The Examiner rejected claims 1-3, 6-20, 23, 24, and 48 as being anticipated by Lyngberg et al. (*J. Ind. Microbiol. Biotech.*, 1999; 23:668-676). This rejection is respectfully traversed.

Lyngberg et al. is the work of two of the inventors of the present application (Lyngberg and Flickinger). Applicants point out that the present application is a national stage filing of PCT US99/21581, which was filed on September 17, 1999, and claims priority to U.S. Provisional Application Serial No. 60/100,914, which was filed on September 17, 1998. A copy of the provisional application is enclosed for the Examiner's convenience as Exhibit C. Also enclosed is a copy of the cover page, table of contents page, and copyright page of the journal in which Lyngberg et al. was published, as Exhibit D. The cover page indicates a University of Minnesota Bio-Medical Library receipt date stamp of August 16, 1999. It is also noted that Figures 3 and 6 of Lyngberg et al. (*J. Ind. Microbiol. Biotech.*, 1999; 23:668-676) correspond to Figures 18 and 19, respectively, of the present application, and Figures 14 and 15, respectively, of the provisional application. Furthermore, claims 1-3, 6-20, 23, 24, and 48 of the present application are the same as those filed in the PCT application, and they are generally supported by the disclosure in the provisional application with respect to the device being designed to detect the presence of a metal (e.g., mercury), which is the subject matter of Lyngberg et al. Thus, withdrawal of this rejection is respectfully requested.

If the Examiner requires a declaration under either 35 U.S.C. Sections 131 or 132, such a declaration can be provided.

### **The 35 U.S.C. §103 Rejection**

The Examiner rejected claims 4 and 5 under 35 U.S.C. §103(a) as being unpatentable over Lyngberg et al. (*J. Ind. Microbiol. Biotech.*, 1999; 23:668-676), and rejected claims 21 and 22 under 35 U.S.C. §103(a) as being unpatentable over Lyngberg et al. (*J. Ind. Microbiol. Biotech.*, 1999; 23:668-676) in view of Anderson et al. (U.S. Patent Application Publication 2001/0041339). For the reasons discussed above with respect to Lyngberg et al., this rejection is respectfully traversed.

**Summary**

It is respectfully submitted that the pending claims 1-24, 48, and 100-108 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the below-listed telephone number if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for  
LYNGBERG et al.

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Sept. 16, 2003  
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**CERTIFICATE UNDER 37 CFR §1.10:**

"Express Mail" mailing label number: EV 073686219 US

Date of Deposit: September 16, 2003

The undersigned hereby certifies that the Transmittal Letter and the paper(s) and/or fee(s), as described hereinabove, are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

By: Sam Her  
Name: Sam Her

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**ATTACHMENT - REPLACEMENT SHEET(S)**

**Serial No.: 09/647,475**

**Docket No.: 110.00810101**

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Pursuant to 37 C.F.R. §1.121(d), attached are amended Figures, labeled "Replacement Sheets," which replace the Figures in the present application.